

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040: Research, Development, Test & Evaluation, Army / BA 5: System Development & Demonstration (SDD)					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev							
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
Total Program Element	-	36.685	44.495	48.264	-	48.264	49.365	46.559	48.906	45.912	0.000	320.186
812: Mil HIV Vac&Drug Dev	-	1.135	1.178	1.201	-	1.201	1.230	1.067	6.069	6.265	0.000	18.145
832: Field Medical Systems Engineering Development	-	19.735	28.821	31.218	-	31.218	31.946	31.413	29.707	29.580	0.000	202.420
849: Infec Dis Drug/Vacc Ed	-	15.815	14.496	15.845	-	15.845	16.189	14.079	13.130	10.067	0.000	99.621

A. Mission Description and Budget Item Justification

This Program Element (PE) funds advanced development of medical materiel within the System Demonstration and Low Rate Initial Production portions of the acquisition life cycle using 6.5 (System Development and Demonstration) funding. It supports products successfully developed in the Systems Integration portion of the Systems Development and Demonstration phases through completion of the Milestone C Decision Review. Commercially-off-the-shelf (COTS) medical products are also tested and evaluated for military use, when available. This PE primarily includes pivotal (conclusive) human clinical trials necessary for licensure by the Food and Drug Administration (FDA).

Projects in this PE include the following:

Project 812 funds military relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development focused on military unique needs effecting manning, mobilization, and deployment. Products from this project will normally transition to Department of Defense (DoD) Health Programs or Other Procurement, Army (OPA) Funds.

Project 832 funds the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. Mature COTS medical products are also evaluated for military use. Consideration will also be given to reduce the medical sustainment footprint through smaller weight and cube volume, or equipment independence from supporting materiel. Products from this project will normally transition to OPA Funds.

Project 849 funds development of candidate medical countermeasures for military relevant infectious diseases. These products fall in four major areas: vaccines, drugs, diagnostic kits/devices, and insect control measures to limit exposure and disease transmission. FDA approval is a mandatory obligation for all military products placed into the hands of medical providers or service members for human use. Products from this project will normally transition to DoD Health Programs or OPA funds.

Project VS8 program receives products that transition from VS7 and funds effort to complete research and development for the medical evacuation (MEDEVAC) Mission Essential Packages (MEPs) to support 256 Medical Evacuation legacy helicopters. The Army's force design increased the number of air frames in the force from 12 to 15 aircraft for 37 MEDEVAC companies to better meet operational needs.

UNCLASSIFIED

Exhibit R-2, RDT&E Budget Item Justification: PB 2020 Army	Date: March 2019
---	-------------------------

Appropriation/Budget Activity 2040: <i>Research, Development, Test & Evaluation, Army I BA 5: System Development & Demonstration (SDD)</i>	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>
--	--

These Projects are managed by United States (U.S.) Army Medical Materiel Development Activity (USAMMDA) and U.S. Army Medical Materiel Agency (USAMMA) of the U.S. Army Medical Research and Materiel Command.

B. Program Change Summary (\$ in Millions)	<u>FY 2018</u>	<u>FY 2019</u>	<u>FY 2020 Base</u>	<u>FY 2020 OCO</u>	<u>FY 2020 Total</u>
Previous President's Budget	39.238	44.542	48.665	-	48.665
Current President's Budget	36.685	44.495	48.264	-	48.264
Total Adjustments	-2.553	-0.047	-0.401	-	-0.401
• Congressional General Reductions	-0.028	-0.047			
• Congressional Directed Reductions	-	-			
• Congressional Rescissions	-	-			
• Congressional Adds	-	-			
• Congressional Directed Transfers	-	-			
• Reprogrammings	-1.210	-			
• SBIR/STTR Transfer	-1.315	-			
• Adjustments to Budget Years	-	-	-0.401	-	-0.401

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 5					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 812 / Mil HIV Vac&Drug Dev			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
812: Mil HIV Vac&Drug Dev	-	1.135	1.178	1.201	-	1.201	1.230	1.067	6.069	6.265	0.000	18.145
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		
A. Mission Description and Budget Item Justification												
This Project funds militarily relevant human immunodeficiency virus (HIV) medical countermeasures. These funds provide for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing. Development is focused on militarily unique needs effecting manning, mobilization, and deployment.												
The major contractor is The Henry M. Jackson Foundation for the Advancement of Military Medicine, Rockville, MD. Research efforts are coordinated with the National Institutes of Health.												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Military HIV Vaccine and Drug Development									1.135	1.140	1.201	
Description: This effort provides funds for engineering and manufacturing development of candidate vaccines and drugs to permit large-scale field testing of vaccines for medical countermeasures to HIV.												
FY 2019 Plans: Will continue support of the Global vaccine effectiveness testing effort. This activity is co-funded by the National Institute of Allergy and Infectious Disease (NIAID) and the Bill and Melinda Gates Foundation. This study is anticipated to take 3.5 years to complete.												
FY 2020 Plans: Continue support to Global Vaccine Candidate clinical trial sites based on a Cooperative Research and Development Agreement (CRADA) with a commercial partner.												
FY 2019 to FY 2020 Increase/Decrease Statement: The minor increase of funding in FY 2020 was due to the inflation factor.												
Title: FY 2019 SBIR/ STTR Transfer									-	0.038	-	
Description: FY19 SBIR/STTR Transfer												
FY 2019 Plans: FY19 SBIR/STTR Transfer												
FY 2019 to FY 2020 Increase/Decrease Statement:												

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019	
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 812 / <i>Mil HIV Vac&Drug Dev</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
FY19 SBIR/STTR Transfer			
Accomplishments/Planned Programs Subtotals		1.135	1.178
FY 2020			
			1.201
C. Other Program Funding Summary (\$ in Millions) N/A			
Remarks			
D. Acquisition Strategy To support testing and evaluation of commercially developed vaccine candidates in government-managed trials.			
E. Performance Metrics N/A			

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army												Date: March 2019			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev						Project (Number/Name) 812 / Mil HIV Vac&Drug Dev			
Management Services (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	2.634	0.199		1.140		1.201		-		1.201	Continuing	Continuing	-
Subtotal			2.634	0.199		1.140		1.201		-		1.201	Continuing	Continuing	N/A
Product Development (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Henry M. Jackson Foundation, : Various	33.545	0.422		-		-		-		-	Continuing	Continuing	Continuing
FY19 SBIR/ STTR Transfer	TBD	N/A : N/A	-	-		0.038		-		-		-	0.000	0.038	-
Subtotal			33.545	0.422		0.038		-		-		-	Continuing	Continuing	N/A
Support (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various : Various	2.038	0.375		-		-		-		-	Continuing	Continuing	-
Subtotal			2.038	0.375		-		-		-		-	Continuing	Continuing	N/A
Test and Evaluation (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Henry M. Jackson Foundation, : Various	27.971	0.139		-		-		-		-	Continuing	Continuing	Continuing
Subtotal			27.971	0.139		-		-		-		-	Continuing	Continuing	N/A

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army											Date: March 2019			
Appropriation/Budget Activity 2040 / 5					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev					Project (Number/Name) 812 / Mil HIV Vac&Drug Dev				
		Prior Years	FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals		66.188	1.135		1.178		1.201		-		1.201	Continuing	Continuing	N/A

Remarks

UNCLASSIFIED

Appropriation/Budget Activity
2040 / 5

Project (Number/Name)	812 / Mil HIV Vac&Drug Dev
------------------------------	----------------------------

R-1 Program Element (Number/Name)
PE 0604807A / Medical Materiel/Medical
Biological Defense Equipment - Eng Dev

[illegible]

UNCLASSIFIED

Exhibit R-4A, RDT&E Schedule Details: PB 2020 Army		Date: March 2019
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) 812 / Mil HIV Vac&Drug Dev

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Global HIV (Ad26/Ad26+gp140) Biologic Lisence Application (BLA) Submission/MS C	1	2024	1	2024
Global HIV (Ad26/Ad26+gp140) BLA Approval	4	2024	4	2024

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 5					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 832 / Field Medical Systems Engineering Development			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
832: Field Medical Systems Engineering Development	-	19.735	28.821	31.218	-	31.218	31.946	31.413	29.707	29.580	0.000	202.420
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		

A. Mission Description and Budget Item Justification

This Project funds the engineering and manufacturing development of medical products for enhanced combat casualty care and follow-on care, including rehabilitation. Specifically funds pivotal (conclusive) human clinical trials or mechanical engineering evaluations for effectiveness of devices or biologics (products derived from living organisms) to fulfill unique military requirements. Consideration is also given to reducing the medical sustainment footprint through smaller weight and cube volume, or equipment independence from supporting materiel. This work is frequently completed through a laboratory/contractor team with the contractor obtaining the U.S. Food and Drug Administration (FDA) licensure for sale of the product.

Major contractors/intra-governmental agencies include: IGR Enterprises, Inc.; Army Medical Department Board Test Center; Se Qual Technologies, Inc.; Enginivity, Inc.; Ultrasound Diagnostician; HemCon Medical Technologies; Cerdak Ltd; Hemerus Medical, LLC; Fast Track Drugs & Biologics, LLC; Integrated Medical Systems, Inc.; the National Institutes of Health National Heart, Lung and Blood Institute (NHLBI); and the U.S. Army Aeromedical Research Laboratory, Walter Reed Army Institute of Research (WRAIR) and Institute of Surgical Research (ISR) for user evaluation. Other military agencies include Program Executive Office (PEO) Soldier, PEO Combat Support/Combat Service Support (CS & CSS), and Naval Undersea Warfare Center.

B. Accomplishments/Planned Programs (\$ in Millions)

	FY 2018	FY 2019	FY 2020
Title: Field Medical Systems Engineering Development PM Medical Devices	2.309	2.644	2.100
Description: This effort funds the engineering and manufacturing development of medical products for enhanced combat casualty care managed by Program Manager (PM)-Medical Devices.			
FY 2019 Plans: Medical Equipment Sets COTS Modernization of Life Cycle Equipment: Will continue development and testing to ensure the most current and cost effective devices are being utilized. Equipment will be selected for modernization based on its own life cycle plan as part of a Sets, Kits and Outfits.			
FY 2020 Plans: Medical Equipment Sets COTS Modernization of Life Cycle Equipment: Will continue development and testing on a reduced number/fewer types of devices (compared to FY19) to ensure the most current and cost effective devices are being utilized. Equipment will be selected for modernization based on life cycle plan as part of a Sets, Kits and Outfits (SKO).			
FY 2019 to FY 2020 Increase/Decrease Statement:			

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019		
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 832 / <i>Field Medical Systems Engineering Development</i>		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
Funding was adjusted in support of the Army's modernization priorities.				
Title: Field Medical Systems Engineering Development PM Pharmaceuticals Description: Funding is provided for engineering and manufacturing development of medical products managed by PM Pharmaceuticals for enhanced combat casualty care and follow-on care, including rehabilitation. FY 2019 Plans: Cryopreserved Platelets: Will complete the Phase 2 safety and effectiveness study in patients with complex cardiac bypass and prepare for of Phase 3 (expanded safety, effectiveness and dosing) pivotal study. Will continue the manufacturing development and validation of Cryopreserved platelet batches. Freeze-Dried Plasma Program: Will continue the Phase 2 prospective clinical trial (safety and efficacy trial that follows patients over time to measure progress/outcomes). FY 2020 Plans: Cryopreserved Platelets: Continuing the new acquisition strategy that was developed and implemented in FY 2018 where a single commercial partner is utilized for the manufacturing development, clinical trials and regulatory processes thru licensure. Continue non-clinical in- Vitro characterization and Phase 2 Clinical Trial efficacy study. Freeze-Dried Plasma Program: Will complete the Phase 2 safety and effectiveness study and prepare for of Phase 3 (expanded safety, effectiveness and dosing) pivotal study. FY 2019 to FY 2020 Increase/Decrease Statement: Funding was adjusted in support of the Army's modernization priorities.		12.601	13.687	8.217
Title: Field Medical Systems Engineering Development PM Medical Support Systems Description: This effort funds the engineering and manufacturing development of medical products managed by PM Medical Support Systems for enhanced combat casualty care and follow-on care, including rehabilitation. FY 2019 Plans: Modernization of medical equipment sets: Will evaluate blood transport products and other commercial items for medical equipment sets. Airworthiness Testing: Will continue to conduct airworthiness testing, required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products covering air and ground medical evacuation.		1.199	1.515	4.559

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army			Date: March 2019		
Appropriation/Budget Activity 2040 / 5		R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev		Project (Number/Name) 832 / Field Medical Systems Engineering Development	
B. Accomplishments/Planned Programs (\$ in Millions)			FY 2018	FY 2019	FY 2020
Medical Evacuation and Treatment Vehicles Medical Equipment Set and Mission Essential Package: Will continue to collaborate with Program Executive Office Ground Combat Systems (PEO GCS) for the implementation of the Medical Equipment Set and Mission Essential Package and user evaluations of the Armored Multipurpose Vehicle.					
Waste Treatment System for the CSH: Testing of waste Treatment System for the CSH.					
Soldier Optimization Decision Aids: Coordinate with PEO Soldier to transition the Environment Health Assessment and Risk Management (EHARM) tool.					
Remote Triage Sensor System: Testing the Remote Triage Sensor System.					
FY 2020 Plans: Modernization of medical equipment sets: Will continue to evaluate the Field Hospital waste water collection system, blood transport products, and other commercial items for medical equipment sets. Airworthiness Testing: Conduct airworthiness testing, required by AR 70-62, for Medical Equipment Set and Mission Essential Package with products covering air and ground medical evacuation. Medical Evac and Treatment Vehicles Medical Equipment Set and Mission Essential Package and CASEVAC: Collaborate with Program Executive Office Combat Support/Combat Service Support for implementation of the CASEVAC system for the Joint Light Tactical Vehicle (JLTV). Waste Treatment System for the CSH: Project was not initiated as planned in FY18. Soldier Optimization Decision Aids (SODA): Will transition the Cold Weather Ensemble Decision Aid and the Heat Strain Decision Aid to Program Executive Office Soldier. Will continue to refine the Environment Health Assessment and Risk Management (eHARM) tool for transition.					
Remote Triage Sensor System: Project was not initiated as planned in FY 2018. Semi-autonomous Casualty Evacuation (CASEVAC) Ground Platform (S-MET): Will collaborate with Program Executive Office Combat Support/Combat Service Support for implementation of the CASEVAC system for the S-MET platform					
Next Generation Uniform Repellent/Impregnation: Will conduct operational assessment and integration into PEO Soldier uniform procurement. Litter Transport Shock/Stressor Mitigation System (Formerly: Next Generation Immobilization System): Will assess system for augmentation and inclusion in medical unit assemblages containing litters.					
FY 2019 to FY 2020 Increase/Decrease Statement: The increase of funding in FY 2020 is due to the planned progression of medical products under development.					
Title: Field Medical Systems Engineering Development -PM Neurotrauma & Psychological Health			3.626	10.029	16.342

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019	
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) 832 / Field Medical Systems Engineering Development	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
<p>Description: This effort funds systems engineering development of medical products managed by Program Manager Neurotrauma & Psychological Health for enhanced combat casualty care and follow-on care, including rehabilitation.</p> <p>FY 2019 Plans: Laboratory Assay for TBI (formerly TBI Diagnostic Assay System) Increment II Point of Care Device: Will begin required validation studies.</p> <p>FY 2020 Plans: Laboratory Assay for Traumatic Brain Injury (TBI) (formerly TBI Diagnostic Assay System) Increment II Point of Care Device: Will conduct required validation studies for testing of a blood assay on the Point of Care Device to aid in the diagnosis of TBI. Will prepare for a submission of the assay for Food and Drug Administration Approval. Will start analysis of data validate how the assay predicts recovery from TBI.</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: Funding increases from FY 2019 to FY 2020 to cover the cost of a pivotal human clinical study for the whole blood assay on the point of care device.</p>			
<p>Title: FY 2019 SBIR/ STTR Transfer</p> <p>Description: FY19 SBIR/STTR Transfer</p> <p>FY 2019 Plans: FY19 SBIR/STTR Transfer</p> <p>FY 2019 to FY 2020 Increase/Decrease Statement: FY19 SBIR/STTR Transfer</p>		-	0.946
Accomplishments/Planned Programs Subtotals		19.735	28.821
C. Other Program Funding Summary (\$ in Millions)			
N/A			
Remarks			
D. Acquisition Strategy			
To support developing in-house or industrial prototypes in government-managed programs to meet military and regulatory requirements for production and fielding.			

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) 832 / Field Medical Systems Engineering Development
E. Performance Metrics N/A		

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army												Date: March 2019			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 832 / Field Medical Systems Engineering Development					
Management Services (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	34.590	3.144		3.172		5.626		-		5.626	Continuing	Continuing	Continuing
Subtotal			34.590	3.144		3.172		5.626		-		5.626	Continuing	Continuing	N/A
Product Development (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Freeze-dried Human Plasma	Various	HemCon Medical Technologies, Inc. : Tigard OR	32.783	-		-		-		-		-	Continuing	Continuing	Continuing
Hypertonic Saline Dextran	Various	National Institutes of Health, National Heart, Lung and Blood Institute (NHLBI) : Various	15.100	-		-		-		-		-	Continuing	Continuing	Continuing
Medical Product Development Cost	Various	Various : Various	6.270	2.306		2.165		-		-		-	Continuing	Continuing	Continuing
Extended Life Red Blood Cell Product	Various	Hemerus Medical, LLC, : Various	3.140	-		-		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	Clinical Research Management, Inc : Hinckley, OH	4.273	2.617		2.940		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	Multiple DoD activities and Dartmouth Hitchcock Med Ctr : North Potomac, MD	14.362	-		-		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	Various	TBD : TBD	1.875	-		-		2.786		-		2.786	0.000	4.661	-
Intracellular Hemorrhage Treatment	TBD	TBD : TBD	0.600	-		-		-		-		-	0.000	0.600	-

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army												Date: March 2019			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 832 / Field Medical Systems Engineering Development					
Product Development (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
TBI Diagnostic Assay System - Increment II (benchtop/POC/ Bandits)	Various	Banyan BioMarkers, Inc : Alachua, FL	0.373	-		-		-		-		-	0.000	0.373	-
Noninvasive Neurodiagnostics	TBD	TBD : TBD	2.647	-		-		-		-		-	0.000	2.647	-
Impedance Threshold Device for the Treatment of Traumatic Brain Injury	TBD	Advance Circulatory Systems Inc. : Roseville, MN	4.387	-		-		-		-		-	0.000	4.387	-
Pre-Hospital Medical Informatics Transport (Ground Transport Telemedicine)	TBD	TBD : TBD	6.321	-		-		-		-		-	0.000	6.321	-
Advanced wound care	Various	TBD : TBD	1.230	-		-		-		-		-	0.000	1.230	-
Junction Noncompressible Hemorrhage	TBD	RevMedX Inc : Wilsonville OR	1.805	-		-		-		-		-	0.000	1.805	-
Laboratory Assay for Traumatic Brain Injury	C/Various	Abbott Laboratories : Chicago, IL	-	2.810		11.002		16.308		-		16.308	Continuing	Continuing	Continuing
FY19 SBIR/ STTR Transfer	TBD	N/A : N/A	-	-		0.946		-		-		-	0.000	0.946	-
Subtotal			95.166	7.733		17.053		19.094		-		19.094	Continuing	Continuing	N/A
Support (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Regulatory Support	Various	Clinical Research Management, Inc., : Various	8.043	0.307		0.332		0.074		-		0.074	Continuing	Continuing	Continuing
Medical Product Development Support Cost	Various	Various : Various	10.209	1.520		-		-		-		-	Continuing	Continuing	Continuing
Medical Equipment Sets Development	Various	Various : Various	2.670	-		-		-		-		-	0.000	2.670	-

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army												Date: March 2019			
Appropriation/Budget Activity 2040 / 5				R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 832 / Field Medical Systems Engineering Development							
Support (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Subtotal			20.922	1.827		0.332		0.074		-		0.074	Continuing	Continuing	N/A
Test and Evaluation (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various : Various	16.023	1.296		-		-		-		-	Continuing	Continuing	Continuing
Cryopreserved Platelets	TBD	TBD : TBD	13.119	2.290		5.106		-		-		-	0.000	20.515	-
Medical Equipment Sets Development	Various	Various : Various	1.206	0.650		3.158		-		-		-	0.000	5.014	-
Freeze Dried Plasma	C/CPFF	TBD : TBD	10.072	2.795		-		6.424		-		6.424	0.000	19.291	-
Subtotal			40.420	7.031		8.264		6.424		-		6.424	Continuing	Continuing	N/A
			Prior Years	FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals			191.098	19.735		28.821		31.218		-		31.218	Continuing	Continuing	N/A
Remarks															

UNCLASSIFIED

Exhibit R-4, RDT&E Schedule Profile: PB 2020 Army

Date: March 2019

Appropriation/Budget Activity

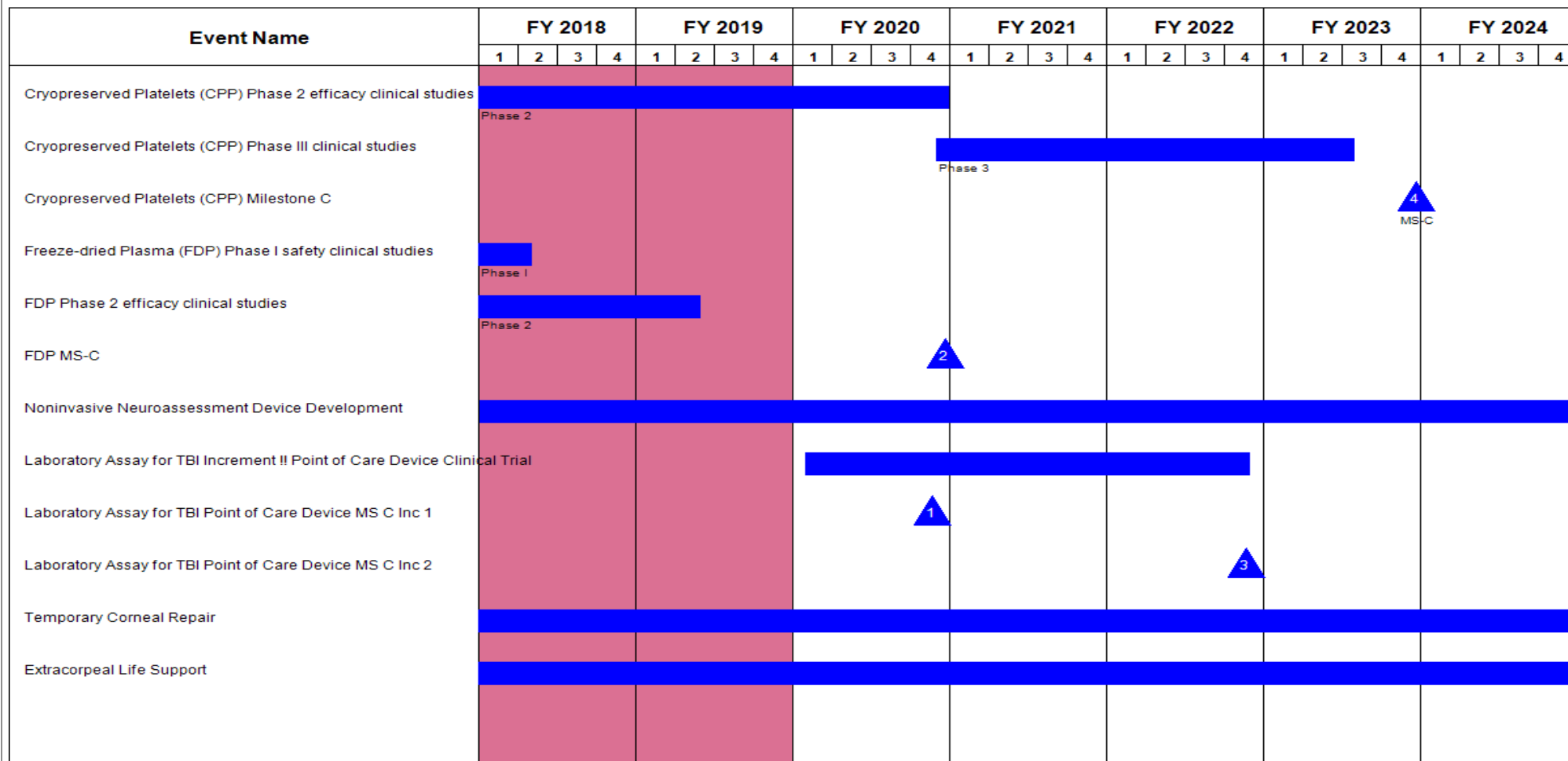
2040 / 5

R-1 Program Element (Number/Name)

PE 0604807A / Medical Materiel/Medical
Biological Defense Equipment - Eng Dev

Project (Number/Name)

832 / Field Medical Systems Engineering
Development



UNCLASSIFIED

Exhibit R-4A, RDT&E Schedule Details: PB 2020 Army			Date: March 2019
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 832 / <i>Field Medical Systems Engineering Development</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Cryopreserved Platelets (CPP) Phase 2 efficacy clinical studies	3	2017	4	2020
Cryopreserved Platelets (CPP) Phase III clinical studies	4	2020	3	2023
Cryopreserved Platelets (CPP) Milestone C	4	2023	4	2023
Freeze-dried Plasma (FDP) Phase I safety clinical studies	3	2014	2	2018
FDP Phase 2 efficacy clinical studies	2	2016	2	2019
FDP MS-C	4	2020	4	2020
Noninvasive Neuroassessment Device Development	1	2017	1	2025
Laboratory Assay for TBI Increment !! Point of Care Device Clinical Trial	1	2020	4	2022
Laboratory Assay for TBI Point of Care Device MS C Inc 1	4	2020	4	2020
Laboratory Assay for TBI Point of Care Device MS C Inc 2	4	2022	4	2022
Temporary Corneal Repair	4	2016	1	2025
Extracorporeal Life Support	4	2016	4	2024

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army										Date: March 2019		
Appropriation/Budget Activity 2040 / 5					R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev				Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed			
COST (\$ in Millions)	Prior Years	FY 2018	FY 2019	FY 2020 Base	FY 2020 OCO	FY 2020 Total	FY 2021	FY 2022	FY 2023	FY 2024	Cost To Complete	Total Cost
849: Infec Dis Drug/Vacc Ed	-	15.815	14.496	15.845	-	15.845	16.189	14.079	13.130	10.067	0.000	99.621
Quantity of RDT&E Articles	-	-	-	-	-	-	-	-	-	-		
A. Mission Description and Budget Item Justification												
<p>This Project funds development of candidate medical countermeasures (MCM: e.g., vaccines, drugs, diagnostic kits/devices) for militarily relevant infectious diseases. This also funds methods to determine if insects are infected with pathogenic organisms thereby posing a risk to service members' and control insect exposure/prevent Warfighters from being bitten by those insects. It funds research that supports conclusive human clinical trials to demonstrate MCM effectiveness safety and related manufacturing tests. This work, which is jointly performed by military laboratories, civilian contracted pharmaceutical firms and foreign research partners, is directed toward the prevention of disease, early diagnosis, and speeding recovery once diagnosed. Medical products approved for human use must meet the U.S. Food and Drug Administration (FDA) approval before MCM can be used on Warfighters. Development priority is based upon four major factors: (1) the extent of the disease within the Combatant Commands' theater of operations, (2) the clinical severity of the disease, (3) the technical maturity of the proposed solution, and (4) the affordability of the solution (development, production, and sustainment). Malaria, dysentery, hepatitis, and Dengue diseases (a severe debilitating disease transmitted by mosquitoes), which are found in all Combatant Command areas and are at the top of the infectious diseases risks list.</p>												
B. Accomplishments/Planned Programs (\$ in Millions)									FY 2018	FY 2019	FY 2020	
Title: Infectious Disease Drug and Vaccine Engineering Development									15.815	14.039	15.845	
Description: Funding for research and development efforts for drugs and vaccines for infectious diseases that are top threats to deployed US forces. Funds research that supports conclusive human clinical trials to demonstrate effectiveness, safety and related manufacturing tests.												
FY 2019 Plans:												
Dengue Tetravalent Vaccine (DTV): Continue to fund Advance Development (AD) candidate vaccine as it enters third year of pivotal phase 3 clinical trial.												
Next Generation Malaria Prophylaxis: Will continue the retinal (eye) safety study (3 year study) started in FY 2017. Address any FDA post-marketing approval requirements.												
Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): The planned submission of the Non-Disclosure Agreement (NDA) did not occur in FY 2017 due to additional testing requirements by the FDA to demonstrate therapeutic equivalence of pre- and post-manufacturing change drug product. The NDA package will be completed and submitted to the FDA for approval in FY 2019. The manufacturing process will be validated in preparation for commercial production of the drug product.												

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019		
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed		
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019	FY 2020
Antimalarial Drug, Artesunate Intravenous: Will support the FDA's inquiries during the review process of the New Drug Application. Will complete required non-clinical study for FDA review.				
Dengue Vaccine Block II: Will continue the development, testing and selection of strains for the dengue human infection model (DHIM) to be used in the early evaluation of dengue vaccine candidates in advance of phase 2 and 3 trials.				
Rapid Diagnostic and Detection Devices (Infectious Disease Diagnostics (Multiple)): The dengue and chikungunya assays will continue to be developed and evaluated. Clinical testing will be conducted for dengue and clinical sites identified for chikungunya.				
FY 2020 Plans: Dengue Tetravalent Vaccine (DTV): Will continue to fund support for Advance Development (AD) candidate vaccine as it enters third year of pivotal phase 3 clinical trial. Malaria Chemoprophylaxis ?Tafenoquine (formerly Next Generation Malaria Prophylaxis): Will continue the retinal (eye) safety study started in FY 2017. Address any FDA post-marketing approval requirements. Topical Antileishmanial Cream (TLC, Paromomycin/Gentamicin): Will conduct safety and therapeutic dose non clinical testing based on FDA guidance. Antimalarial Drug, Artesunate Intravenous: Will conduct required non-clinical study for FDA review. Dengue Vaccine Block II: Will continue the development, testing and selection of strains for the dengue human infection model (DHIM) to be used in the early evaluation of dengue vaccine candidates in advance of phase 2 and 3 trials under PE 0603807A, Project 808.				
Rapid Diagnostic and Detection Devices (Formerly Infectious Disease Diagnostics (Multiple)): The dengue and chikungunya assays will continue to be developed and evaluated. Clinical testing will be conducted for dengue and clinical sites identified for chikungunya.				
FY 2019 to FY 2020 Increase/Decrease Statement: The increase of funding in FY 2020 is due to the planned progression of multiple infectious disease medical products in development. Funding will support the FDA requirements for clinical trials for those products.				
Title: FY 2019 SBIR/STTR Transfer		-	0.457	-
Description: FY19 SBIR/STTR Transfer				
FY 2019 Plans: FY19 SBIR/STTR Transfer				
FY 2019 to FY 2020 Increase/Decrease Statement:				

UNCLASSIFIED

Exhibit R-2A, RDT&E Project Justification: PB 2020 Army		Date: March 2019	
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 849 / <i>Infec Dis Drug/Vacc Ed</i>	
B. Accomplishments/Planned Programs (\$ in Millions)		FY 2018	FY 2019
FY19 SBIR/STTR Transfer			
Accomplishments/Planned Programs Subtotals		15.815	14.496
C. Other Program Funding Summary (\$ in Millions) N/A			
Remarks			
D. Acquisition Strategy To support testing and evaluation of in-house and commercially developed products in government-managed trials to meet FDA requirements and Environmental Protection Agency registration.			
E. Performance Metrics N/A			

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army												Date: March 2019			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev						Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed			
Management Services (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Management Services Cost	Various	Various : Various	20.862	0.877		0.927		0.804		-		0.804	Continuing	Continuing	Continuing
Medical Product Development Management Services Cost	C/CPFF	General Dynamics Information Technology : Frederick MD	6.780	4.105		2.749		2.307		-		2.307	0.000	15.941	-
Subtotal			27.642	4.982		3.676		3.111		-		3.111	Continuing	Continuing	N/A
Product Development (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Cost	Various	Various : Various	37.555	0.963		1.644		3.528		-		3.528	Continuing	Continuing	Continuing
Topical Antileishmanial Drug	TBD	TBD : TBD	2.400	-		-		2.414		-		2.414	0.000	4.814	-
Topical Antileishmanial Drug	C/TBD	Advantar Laboratories, INC : TBD	2.207	0.479		-		0.864		-		0.864	0.000	3.550	-
Dengue Tetravalent Vaccine	TBD	TBD : TBD	2.047	-		-		-		-		-	0.000	2.047	-
Hemorrhagic Fever W/ Renal Syndrome	C/TBD	TBD : TBD	1.000	-		-		-		-		-	0.000	1.000	-
FY19 SBIR/ STTR Transfer	TBD	N/A : N/A	-	-		0.457		-		-		-	0.000	0.457	-
Subtotal			45.209	1.442		2.101		6.806		-		6.806	Continuing	Continuing	N/A

UNCLASSIFIED

Exhibit R-3, RDT&E Project Cost Analysis: PB 2020 Army												Date: March 2019			
Appropriation/Budget Activity 2040 / 5						R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev						Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed			
Support (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development Support Cost	Various	Various : Various	19.380	-		0.157		-		-		-	Continuing	Continuing	Continuing
Medical Product Development Support Cost	PO	Clinical Research Management, In : Hinckley, OH	5.407	0.976		-		0.220		-		0.220	0.000	6.603	-
Subtotal			24.787	0.976		0.157		0.220		-		0.220	Continuing	Continuing	N/A
Test and Evaluation (\$ in Millions)				FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total			
Cost Category Item	Contract Method & Type	Performing Activity & Location	Prior Years	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Award Date	Cost	Cost To Complete	Total Cost	Target Value of Contract
Medical Product Development T&E Cost	Various	Various : Various	46.360	4.960		0.805		-		-		-	Continuing	Continuing	Continuing
Dengue Tetravalent Vaccine	TBD	WRAIR/AFRIMS : Silver Spring MD	0.952	0.450		0.590		0.500		-		0.500	0.000	2.492	-
Dengue Tetravalent Vaccine	C/TBD	TBD : TBD	2.156	3.005		1.151		2.635		-		2.635	0.000	8.947	-
Product Development of Dengue Tetravalent Vaccine	Various	TBD : TBD	4.530	-		-		-		-		-	0.000	4.530	-
Next Generation Malaria Prophylaxis	C/Various	TBD : TBD	-	-		3.421		2.573		-		2.573	0.000	5.994	-
Dengue Vaccine block II	C/Various	TBD : TBD	-	-		2.595		-		-		-	0.000	2.595	-
Subtotal			53.998	8.415		8.562		5.708		-		5.708	Continuing	Continuing	N/A
			Prior Years	FY 2018		FY 2019		FY 2020 Base		FY 2020 OCO		FY 2020 Total	Cost To Complete	Total Cost	Target Value of Contract
Project Cost Totals			151.636	15.815		14.496		15.845		-		15.845	Continuing	Continuing	N/A
Remarks															

UNCLASSIFIED

Exhibit R-4, RDT&E Schedule Profile: PB 2020 Army **Date:** March 2019

Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / Medical Materiel/Medical Biological Defense Equipment - Eng Dev	Project (Number/Name) 849 / Infec Dis Drug/Vacc Ed
--	--	--

Event Name	FY 2018				FY 2019				FY 2020				FY 2021				FY 2022				FY 2023				FY 2024			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials																												
	FY11-FY18																											
DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review																												
DTV Biologic Licensing Application (BLA) Submission																												
DTV BLA Approval																												
Malaria Prophylaxis (MS-C) Engineering, Manufacturing and Development phase																												
Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development																												
Paromomycin/Gentamicin TLC New Drug Application (NDA)																												
Paromomycin/Gentamicin TLC FDA Approval																												
Paromomycin/Gentamicin TLC (Fielding / Delivery)																												
Leishmania Rapid Diagnostic Device (Fielding / Delivery)																												
Hemorrhagic Fever with Renal Syndrome Clinical Studies																												
Dengue Vaccine Block II Adult Indication Studies																												
Dengue Vaccine Block II OCONUS Clinical Trials																												

UNCLASSIFIED

Exhibit R-4A, RDT&E Schedule Details: PB 2020 Army			Date: March 2019
Appropriation/Budget Activity 2040 / 5	R-1 Program Element (Number/Name) PE 0604807A / <i>Medical Materiel/Medical Biological Defense Equipment - Eng Dev</i>	Project (Number/Name) 849 / <i>Infec Dis Drug/Vacc Ed</i>	

Schedule Details

Events	Start		End	
	Quarter	Year	Quarter	Year
Dengue Tetravalent Vaccine (DTV) Phase 3 Pivotal Clinical Trials	1	2011	2	2019
DTV Phase 2 Adult Traveler / Military Indication Studies	2	2012	1	2017
DTV Milestone C (MS-C) Engineering, Manufacturing and Development phase review	1	2022	1	2022
DTV Biologic Licensing Application (BLA) Submission	2	2020	2	2020
DTV BLA Approval	2	2021	2	2021
Malaria Prophylaxis (MS-C) Engineering, Manufacturing and Development phase	4	2018	4	2018
Paromomycin/Gentamicin TLC Phase 3 Safety and Effectiveness Clinical Trial	1	2016	1	2017
Paromomycin/Gentamicin TLC (MS-C) Engineering, Manufacturing and Development	4	2019	4	2019
Paromomycin/Gentamicin TLC New Drug Application (NDA)	3	2020	3	2021
Paromomycin/Gentamicin TLC FDA Approval	4	2021	4	2021
Paromomycin/Gentamicin TLC (Fielding / Delivery)	4	2021	4	2024
Leishmania Rapid Diagnostic Device (Fielding / Delivery)	1	2015	4	2020
Hemorrhagic Fever with Renal Syndrome Clinical Studies	1	2016	4	2020
Dengue Vaccine Block II Adult Indication Studies	1	2016	4	2020
Dengue Vaccine Block II OCONUS Clinical Trials	1	2016	4	2020